

REMARKS

Claims 20-52 are pending in this application. Claim 20, 28-32, 40, 41, and 51 have been amended. Support for the claim amendments may be found on page 8, paragraph 2, of the specification. No new matter has been added.

This issues outstanding in the application are as follows:

- Claim 32 has been objected to because of informalities.
- Claims 31 and 33-41 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description.
- Claims 28-30, 40, 41, 51, and 52 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled by the written description.
- Claims 20-41 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.
- Claim 41 has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Liao *et al.*
- Claims 42-50 have been allowed.

I. Claim objections

The Examiner has objected to claim 32 because the gene “ftsA” appears twice in the Markush group. Claim 32 has been amended and does not contain any informalities.

II. 35 USC 112, first paragraph rejections

The Examiner has rejected claims 31 and 33-41 under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description.

Claim 31 – “cell division gene”

A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). It is submitted that the term “cell division gene” used in claim 31 is a term known to one with skill in the art and hence that the skilled person would therefore be able to identify what is, and what is not, a cell division gene.

The skilled person would understand that cell division genes are a group of genes identified by mutations giving rise to a cell division defective phenotype. As evidence that the term is one of art, a number of reviews have been published on the subject of cell division that refer to cell division genes. A copy of reviews by Margolin (*Themes and variations in prokaryotic cell division* - FEMS Microbiol. Rev. (2000) 24: pages 531 to 548) and Errington, Daniel and Scheffers (*Cytokinesis in bacteria* – Microbiol. Mol. Biol. Rev. (2003) 67: pages 52-65) are attached.

The Margolin review provides an overview of prokaryotic cell division and uses the term cell division gene (see page 537, right hand column, first paragraph and page 537, left hand column of Margolin). The Margolin citation also refers extensively to cell division proteins i.e. those proteins encoded by the cell division genes (see for example: page 532, left hand column, final paragraph; page 533, right hand column, third paragraph; page 536, left column, first paragraph; and Table 2 on page 533). The review by Errington *et al* also refers to cell division proteins (see for example: Tables 1 and 2 on page 53; page 56, right hand column, second paragraph; and page 58, right hand column, penultimate paragraph).

As the term cell division used in claim 31 is one known to one skilled in the art, the claimed invention is adequately described and it would be apparent to the skilled person that the inventor was in possession of the invention at the filing date. In light of the above arguments, Applicant respectfully requests withdrawal of the 35 U.S.C. § 112, first paragraph rejection of claim 31.

Claims 28 -30, 40, 41, 50 and 52 – “growth”

Claims 28- 30, 40, 41, 50 and 52 have been amended without prejudice or acquiescence to replace the term “growth” with the term “outgrowth” in order to advance prosecution of the application. Support for the amendment may be found on page 8, paragraph 2, of the specification, which refers to “outgrowth of a new colony.” Applicant thus requests that the 35 U.S.C. § 112, first paragraph rejection of claims 28- 30, 40, 41, 50 and 52 be withdrawn in light of the claim amendments.

III. 35 USC 112, Second Paragraph

The Examiner has rejected claims 20-41 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Claim 20 has been amended now refers to “a DNA” rather than “the DNA”. Claim 28 has been amended so that the preamble of the claim and the outcome set forth in the terminal step match. Claim 31 has been amended so that claim 31 now specifies that the second reporter gene provides a measure of the total synthesis of σ^F or σ^E factor, rather than a measure of the amount of inactive σ^F or σ^E factor . In light of the above claim amendments, Applicant respectfully requests withdrawal of the 35 U.S.C. § 112, second paragraph rejection.

IV. 35 USC 102(b) rejection

The Examiner has rejected claim 41 as allegedly lacking novelty over Liao *et al* (*J. Bacterial* (1997) 179: 1490-1496).

Patent law requires that “a rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference.” *In re Paulsen*, 30 F.3d 1475, 31 U.S.P.Q. 2d 1671 (Fed. Cir. 1994). Claim 41 has been amended so that it now refers to a method of preparing a composition for use in killing or inhibiting the outgrowth of bacteria. The method of claim 41 involves carrying out the assay method of claim 40, which uses one of the *bacillus* strains of the invention, and then formulating the agent identified in the assay into a composition.

Liao *et al* does not disclose any of the *bacillus* strains of the invention in which a gene has been replaced by its homologue from another bacterium. As the method of claim 41 specifically involves using one of the *bacillus* strains of the invention the subject matter of

claim 41 must therefore be novel over Liao *et al.* Applicant contends that a proper *prima facie* case of anticipation has not been made because identity is clearly lacking. Accordingly, Applicant respectfully requests this rejection be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. According, the Examiner is respectfully requested to pass this application to issue.

A check in the amount of \$55 for a one-month extension of time is enclosed herewith. Applicant believes no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02186US0 from which the undersigned is authorized to draw.

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Respectfully submitted,


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